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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/989,362	12/12/97	GORMAN	D	DX0686

HM11/0901

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EXAMINER	
TUNG, M	

ART UNIT	PAPER NUMBER
1644	3

DATE MAILED: 09/01/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 08/989,362	Applicant(s) Gorman And Mattson
	Examiner Mary Tung	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *0* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

CRF Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

2. The claims recite the amino acid and nucleotide sequences. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under *35 U.S.C. § 121:*

I. Claims 1-6 drawn to a protein, composition, and kit, classified in class 530, subclasses 300 and 350; class 424, subclasses 185.1 and 193.1; class 514, subclass 21.

II. Claims 7-9 drawn to an antibody and kit, classified in class 530, subclasses 387.9 and 391.3.

III. Claim 10, drawn to a method of purifying protein using antibody, classified in class 530, subclass 413.

IV. Claims 11-17, drawn to a nucleic acid, vector, host cell and kit, classified in class classified in class 536, subclasses 23.5, 24.3 and 24.33; class 435, subclasses 320.1, 325, 348, 352, 366, 252.1 and 255.1.

V. Claim 18, drawn to a method of modulating physiology or development of a cell, classified in class 435, subclasses 375 and 377.

VI. Claims 19 and 20, drawn to a method of modulating the physiology of a cell, classified in class 435, subclasses 69.1 and 375.

4. Groups I, II and IV are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

5. Groups III, V and VI are unique methods. They differ with respect to ingredients and method steps. The method of purifying a protein using an antibody, recited in Group III, would not suggest the method of modulating the physiology or development of a cell using an agonist or antagonist, recited in Group V. Nor would the methods of Groups III and V suggest the method of modulating the physiology of a cell using a 499E9 protein, antibody or nucleic acid recited in Group VI. Additionally, a method of treating a cell in Group V would involve different steps, reagents and materials than a treatment of a mammal in Group VI. They are therefore, patentably distinct each from the other.

~~because a search of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner~~.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because a search of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

7. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121:

8. If Groups I-III are elected, the applicant is further required to elect a **specific** embodiment: a protein attached to a substrate or a protein conjugated to a chemical moiety.

9. If Group IV is elected, the applicant is also required to elect a **specific embodiment**: a nucleic acid less than 6 kb or a full-length nucleic acid.

10. If Group IV is elected the applicant is further required to elect a **species:** a cell or tissue. If cell is elected, then applicant is further required to elect a **species:** prokaryotic, eukaryotic, bacterial, yeast, insect, mammalian, mouse rodent or human cell.

11. If Group V is elected, the applicant is further required to elect a **specific method**: modulating physiology of a cell or modulating the development of a cell.

12. If Group V is elected the applicant is further required to elect an **embodiment:** introducing an agonist or antagonist.

13. If Group VI is elected, the applicant is further required to elect a **specific embodiment**: contacting cell with 499E9 protein, antibody or nucleic acid.

14. If Group VI is elected the applicant is further required to elect a **specific embodiment:** apoptosis of T cell or activation of T cell.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

18. The following claim(s) are generic: claims 1, 7, 11, 18 and 19.

19. The species are distinct each from the other for the following reasons:

20. The recited products, protein, antibody or nucleic acid have different biochemical characteristics, structure and functions.

21. The recited cells or tissue are different in their properties, morphological appearances and physiological function.

22. Modulation the physiology of a cell or modulating the development of a cell requires different steps and reagents and would result in different intended outcomes.

23. Introduction of an agonist or antagonist into a cell requires different steps and reagents and would result in different intended outcomes.

24. Apoptosis of T cells and activation of T cells are opposite cellular responses and would be measured using different reagents, steps and involve different cellular mechanisms.

25. A telephone call to request an oral election was not made due to the complexity of the restriction and the requirement to comply with sequence rules.

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with *37 C.F.R.* § *1.48(b)* if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under *37 C.F.R.* § *1.48(b)* and by the fee required under *37 C.F.R.* § *1.17(h)*.

26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Mary B Tung

August 28, 1998
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640

Application No.: 08/989,362

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

- [ ] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-0400

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE